

applicants carefully pointed out the errors in replying to every ground of objection and rejection in the February 3, 1998 Action.

Second, the March '01 Communication was untimely and improper. On that basis alone, it should be withdrawn.

Third, applicants respectfully maintain that the Administrative Requirement is unjust and contrary to law. In particular, none of 37 C.F.R. § § 1.56, 63, and 78(b) support or sanction the Administrative Requirement, nor the affirmative duties it seeks to unjustly impose.

Fourth, to the extent the PTO seeks to maintain the Administrative Requirement, the "rejection" based thereon should be maintained as provisional and held in abeyance until other issues on the merits are resolved and the application is otherwise in form for consideration and allowance.

Fifth, any administrative action, such as abandonment of the application, allegedly authorized by and undertaken pursuant the Administrative Requirement, should be deferred because it would be premature in view of the fact that applicants' challenge to the Administrative Requirement is still pending before the Commissioner on petition.

Applicants respectfully request reconsideration and allowance of this application in view of the following remarks.

I. DESCRIPTION OF THE ACTIVITIES PRIOR TO THIS RESPONSE

This application is one of a number of related applications filed by applicants. Applicants originally filed Application Serial No. 317,510 on November 3, 1981 (1981 Application). The 1981 Application issued as U.S. Pat. No. 4,694,490. Applicants have filed a series of continuation and continuation-in-part applications based on the 1981 Application. Application Serial No. 096,096 filed September 11, 1987 (1987 Application) is a continuation-in-part of the 1981 Application. Subsequent applications include the disclosure of this continuation-in-part application.

On August 30, 1993, Application Serial No. 08/113,329 ('329 Application) was filed. In

the period between March 2, 1995, and June 7, 1995, applicants filed 328 applications, including the instant application, which were continuations of the '329 Application. Accordingly, the '329 Application and its 328 continuations represented a total of 329 related applications. These related applications were disclosed to the PTO in compliance with applicants' duty of disclosure under 37 C.F.R. § 1.56.

During the prosecution of this application, the PTO mailed the February 3, 1998 Action, which was made final. The February 3, 1998 Action included, *inter alia*, an assertion that conflicting claims exist between applicants' related applications. The assertion was supported with an appendix comparing 5 pairs of claims selected from the related applications. Notably, none of the claims in the appendix were selected from this application. In order to resolve the alleged potential conflicts between applications, the Administrative Requirement was imposed. The Administrative Requirement compels applicants to either:

- (1) file terminal disclaimers in each of the related applications terminally disclaiming each of the other applications, or
- (2) file an affidavit attesting to the fact that all claims in the applications have been reviewed by applicant and that no conflicting claims exists between the applications, or
- (3) resolve all conflicts between claims in the related applications by identifying how all the claims in each application are distinct and separate inventions from all the claims in the other related applications.

The February 3, 1998 Action asserted that failure to comply with this Administrative Requirement would result in abandonment of this application. The Administrative Requirement was also imposed in many of applicants' copending applications.

Applicants timely filed the August 3, 1998 Response in response to the February 3, 1998 Action. In the August 3, 1998 Response, applicants specifically addressed the Administrative Requirement. Applicants demonstrated that the Administrative Requirement was improperly imposed. Applicants also properly responded to all other issues raised in the February 3, 1998 Action.

Applicants' amendment filed April 13, 2000 added claims to the instant application in consonance with the consolidation agreement with the PTO.

In order to advance the prosecution of these related applications, from November 1998 through June 1999, applicants' representatives conducted a series of interviews with PTO management. During these interviews, senior PTO management suggested that further examination of applicants' related applications could be expedited by reducing the number of pending applications.

In response to this suggestion, applicants agreed to consolidate the claims into 56 subject matter groups. The PTO then indicated that the claims in each group are not patentably distinct and that it would be proper and desirable to examine all of the claims together.

Accordingly, for each subject matter group the applications were separated based on whether priority was claimed to the 1981 Application or the 1987 Application. The claims from all applications in a group with the same priority claim were added to a single application designated an "A" Application. There are currently 79 "A" applications pending. The remaining applications were abandoned with the exception of one "B" Application corresponding to each "A" Application.

According to this arrangement, the PTO agreed to hold prosecution of the "B" applications in abeyance pending final action in the corresponding "A" applications. Applicants and the PTO agreed that, in order to expedite allowance of patentable claims, if there were claims that remained finally rejected in an application, those claims were to be moved to the "B" Application for further action, and the "A" Application would be allowed to issue. This agreed-upon process was diagramed in a flowchart produced at an interview with Examiner Faile on February 25, 1999, and is attached as Exhibit A. An additional acknowledgement by the PTO confirming this "consolidation agreement" appears in the PTO's Notices mailed on January 16 and January 18, 2001.¹ Further acknowledgements by the PTO confirming the consolidation

¹ These notices were mailed in connection with Application Serial Nos.: 08/459,216, 08/438,206, 08/438,659, 08/437,044, 08/437,937, 08/440,837, 08/483,980, 08/442,165, 08/442,335, 08/442,507, 08/482,573, 08/445,290, 08/446,429, 08/449,413, 08/449,800, 08/483,054, 08/449,702, 08/449,110, 08/483,174, 08/469,078, 08/471,024, 08/470,476, 08/477,564, 08/487,649, and 08/478,794. The PTO's acknowledgement of the consolidation agreement in the January 16 and 18, 2001 Notices comes in the form of an assertion that applicants did not complete the consolidation process in a timely manner. Applicants refuted this allegation in responses filed on March 19, 2001 to each of the above identified applications' attached Appendix B beginning at page 18.

agreement appear in Office Actions and correspondence in applicants' related cases.²

In good faith reliance on the consolidation agreement, applicants abandoned 169 of their 329 pending applications. Applicants filed numerous amendments adding to the designated "A" applications various claims that had been pending in the abandoned applications and the designated "B" applications. In so doing, applicants incurred costs of over \$500,000 in filing fees alone in order to comply with the consolidation agreement.

On March 7, 2000, applicants filed a petition to the Commissioner under 37 C.F.R. § 1.181 for application serial number 08/470,571 requesting that the Examiner be required to withdraw the improper Administrative Requirement. Applicants have received no action on this petition to date.

On March 21, 2001, the PTO mailed the March '01 Communication, which asserts that the April 13, 2000 Response is not fully responsive to the February 3, 1998 Action for failure to comply with the Administrative Requirement.

II. APPLICANTS' SUBMISSIONS WERE FULLY RESPONSIVE TO THE FEBRUARY 3, 1998 ACTION AND IN FULL COMPLIANCE WITH 37 C.F.R. § 1.111

A review of the instant application demonstrates that the August 3, 1998 Response(s) and the April 13, 2000 Response (collectively, the "Responses") unquestionably comply with 37 C.F.R. § 1.111. In accordance therewith, the Responses are, and do appear throughout to be, a *bona fide* attempt to advance the application to final action. In their Responses, applicants addressed each and every of the many objections and rejections raised by the Examiner in the February 3, 1998 Action, including a multiple page response to the Administrative Requirement.

In fact, the completeness of the Responses is tacitly acknowledged by the PTO's failure to object to the initial August 3, 1998 Response for years after the August 3, 1998 Response.

² See, e.g., the June 8, 2000 PTO interview summary, a copy of which was filed as Appendix D in applicants' responses filed on March 19, 2001 to each of the applications identified in footnote 1.

Moreover, the circumstances indicate that the PTO had initially considered the Response to be responsive. This is confirmed by the extensive period of time that has passed and by the extensive interviews that took place.

In view of the circumstances described above, Applicant's response was fully responsive and the requirement of the March '01 Communication should be withdrawn.

III. THE MARCH '01 COMMUNICATION IS UNTIMELY AND IMPROPER

In the March '01 Communication, the Examiner now contends at this late date that the August 3, 1998 Response(s) and April 13, 2000 Response were not fully responsive to the February 3, 1998 Action. The communication is untimely and improper.

The assertion that the Responses were nonresponsive is untimely. After filing the August 3, 1998 Response, applicants conducted a series of interviews with PTO management from November '98 through June '99. At no point during these discussions did the PTO indicate or even suggest that the response for this application (or any other co-pending related application) was nonresponsive based on the Administrative Requirement.

To now assert, some **32 months** after applicants' original response in this application, that the response for this application was nonresponsive, is untimely. Moreover, making the assertion after the PTO had conducted extensive interviews during a six month period without making mention of this "deficiency," simply highlights the overall inequity of the Examiner's action.

Not only does a basic sense of fairness counsel that the March '01 Communication is untimely; so does the Manual of Patent Examining Practice (MPEP). Section 714.05 of the MPEP mandates that "[a]ctions by applicants . . . should be inspected immediately upon filing to determine whether they are completely responsive to the preceding Office action so as to prevent

abandonment of the application.” Thus, the MPEP expressly instructs the Examiner to examine responses promptly in order to avoid abandonment.

Here, the Examiner did not comply with the MPEP’s dictate, yet the Examiner is explicitly threatening to abandon this and other co-pending applications. By not complying with the requirements of the MPEP himself, the Examiner has placed this and other co-pending applications at risk of the very thing the MPEP seeks to avoid — abandonment. This is improper.

In sum, applicants respectfully submit that the March ’01 Communication is untimely and improper and, on that basis alone, the requirement of the March ’01 Communication should be withdrawn.

IV. THE ADMINISTRATIVE REQUIREMENT IS UNJUSTIFIED, UNSUPPORTED BY LEGAL AUTHORITY AND IMPOSED IN VIOLATION OF THE ADMINISTRATIVE PROCEDURES ACT

In the February 3, 1998 Action, the Examiner imposed the following Administrative Requirement on applicants. The February 3, 1998 Action compels applicants to: 1) file terminal disclaimers in each of applicants’ related applications; 2) provide an affidavit stating that no conflicting claims exists between the applications and identifying the specific steps taken to insure that no conflicting claims exist between the applications; or 3) resolve all conflicts between claims in the various applications.

By explicitly requiring applicants to comply with one of these requirements to obtain allowance of the application, the Examiner has imposed a condition that will result in abandonment if applicants fail to comply with the Administrative Requirement. Applicants should not be forced to comply because the Administrative Requirement is unjustified and unsupported by applicable law and regulations, and because the Administrative Requirement

constitutes an unlawfully promulgated substantive rule which contradicts the PTO's established regulatory scheme.

A. The Examiner's Imposition Of The Administrative Requirement Is Unjustified

1. The Allegation That Examination Is Burdensome And Onerous Is Obviated By Applicants' Extensive Submissions

The Examiner's justification for imposing the Administrative Requirement is that an analysis of all claims in the then-pending 328 related application³ would be an extreme burden on the PTO requiring millions of claim comparisons. Contrary this assertion, the burden of comparing the claims in the pending application to the claims in other related applications is manageable within the context of an examination of a patent application for patentability. Such an examination includes, for instance, a determination that the claims are not obvious in view of all printed publications, including millions of issued U.S. patents published more than a year prior to the filing date of the application. Of course, the PTO does not compare each pending claim to every printed publication, but rather relies on the expertise of the Examiner and careful classification of prior patents and technical literature to focus on the prior art that is most pertinent.

In this case, applicants have diligently worked to educate the Examiner regarding classifications and the differences between the claims of the co-pending applications. Specifically, applicants have provided the PTO with applicants' classifications of the various applications and have submitted extensive documents on paper and in electronic form to assist the Examiner in analyzing and comparing the claims at issue. Applicants and their

³ The Examiner's assertion regarding the burden is largely overcome by events now that 169 of the 329 applications have been abandoned pursuant to the consolidation agreement between applicants and the PTO. This point illustrates the difficulties that are created by the PTO's untimely response on this issue and why any double patenting rejection should be held in abeyance until other prosecution issues are fully resolved. See Section V, *infra*.

representatives have conducted numerous interviews in an effort to answer all the Examiner's questions as to claims distinctions and similarities. In fact, after applicants provided the various conceptual groups used by applicants to classify and organize the pending applications, the PTO requested that all claims in each group be consolidated into groups of two to four applications. Applicants complied with this request in an effort to eliminate any excessive burden of claim comparison on the Examiner. In sum, applicants have submitted all information necessary to enable the Examiner to focus on the most pertinent claims for comparison under a double patenting analysis.

Despite applicants' efforts to work with the PTO in providing supplemental material to assist with the Examiner's task of claim comparisons, the Examiner has imposed the Administrative Requirement which effectively requires applicants to compare the claims and make a determination for the Examiner on the double patenting issue. When an Examiner is unable to articulate any reason for rejecting a patent application, 35 U.S.C. § 131 mandates issuance. By requiring a statement from applicants regarding conflicting claims, the Examiner has ignored the material submitted by applicants to assist the Examiner in making such claim comparisons. The Examiner can not ignore the record made by applicants as to the relationship among the claims and simply require a blanket statement which ignores the facts of record. Considering the record in the case and the materials applicants have submitted, the Examiner is not justified in electing not to examine each case in order to make proper and complete determinations on the double patenting issue.

2. The Examiner Has A Duty To Examine An Application

Under 35 U.S.C. § 131, the Commissioner “shall cause an examination to be made of the application . . . and if on such examination it appears that the applicant is entitled to a patent under the law, the Commissioner shall issue a patent therefor.” The statute clearly mandates an examination to occur on behalf of the Commissioner through his agent, the Examiner. The use of the mandatory word “shall” imposes a duty on the examiner which may not be shifted to applicants. The duty to examine is the examiner’s primary role. *See also* 35 U.S.C. §§ 101-103 (A person shall be entitled to a patent unless —”)

Moreover, under 35 U.S. C. § 132, “[w]henever, on examination, any claim for a patent is rejected ... the Commissioner shall notify the applicant thereof, stating the reasons for such rejection” This statute provides that the Commissioner must give reasons for rejecting a claim for a patent. MPEP § 706 provides that the “goal of examination is to clearly articulate any rejection early in the prosecution process so that the applicant has the opportunity to provide evidence of patentability and otherwise reply completely at the earliest opportunity.” 37 C.F.R. § 1.104 further delineates the examiner’s duty to examine and provide reasons for any and all rejections of a patent.

The facts at hand show that applicants have fully complied with their obligations under the Patent Statute, while the Examiner has effectively attempted to abrogate his statutorily-assigned obligation to conduct a full examination and notify the applicants of the specific reasons for the rejection of any claims.

First, applicants endeavored in good faith to present non-conflicting claims in the initially filed applications. Evidence of applicants’ good faith is further demonstrated by their consolidation of the applications into 56 subject matter categories and abandonment of 169

applications. **Second**, applicants fully disclosed all information known to be material to patentability. In particular, applicants disclosed the identity of all related copending applications that might be relevant to any obviousness-type double patenting analysis that the Examiner might see fit to conduct. **Third**, with applicants having disclosed all such knowledge in their possession, it is now the Examiner's duty to accept or reject applicant's position. **Finally**, if applicants' position is rejected, the Examiner must provide a reasoned basis as to why so that applicants can address the Examiner's specific rejections.

Turning to the specifics of this application, the Examiner attempts to shift the burden of examination and notification onto applicants through an untenable reinterpretation of the patent regulations. The Examiner argues in the March '01 Communication that "under 37 C.F.R. § 1.63 and § 1.56, the applicants are required to 1) review and understand the contents of each specification, including all claims and amendments, and **2) eliminate conflicting claims or notify the Office of conflicting claims.**" March '01 Communication, P. 4 (emphasis added). There is no support whatsoever found in the text of either rule for the Examiner's second contention. Moreover, applicants are not aware of any case law or other authority supporting the Examiner's proposition that Rule 56 and 63 cooperate to create an affirmative duty on applicants to preemptively perform double patenting analysis and to identify to the Examiner any claims that applicants "believes" or "knows" are conflicting.

Applicants acknowledge their duty to disclose all information known to be material to patentability. As set forth above, applicants have complied with their duty in disclosing all co-pending claims to the Examiner. Contrary to the Examiner's novel interpretation, Rules 56 and 63 do not require an applicant to affirmatively make a determination in order to identify claims that **may** conflict. If an applicant "knew" that certain claims conflicted then perhaps applicants

might be obliged to notify the Office of conflicting claims. However, absent such knowledge, no law or regulation places a burden upon applicants to examine and compare each co-pending claim and make a conclusive determination on the issue of double patenting.⁴ It is the Examiner's responsibility, not applicants', to identify claims that arguably do conflict and articulate those arguments as to why such claims do conflict. For applicants to undertake this task, as the Examiner suggests, would effectively reverse the examination process mandated by statute under which the Examiner has the burden and the duty to determine whether and why a claim should be rejected for double patenting.

The Examiner's conclusion that the Administrative Requirement "is not controversial" fails to take into account the applicants' perspective on this issue. Rather than conducting a thorough examination and articulating his basis for a rejection in the instant application, the Examiner has essentially presumed obvious-type double patenting and has required applicants to resolve the issue of obviousness-type double patenting by complying with the Administrative Requirement. Even if the Administrative Requirement was justified or proper, none of the options presented in the requirement are reasonable, practical or prudent.

If applicants were to concede the validity of the double patenting rejection by filing terminal disclaimers, they may lose years of patent coverage. A loss of valuable years of coverage is an unreasonable and unfair result when the Examiner has failed to establish a prima facie case of obviousness-type double patenting.

If applicants were to traverse the double patenting rejection under the second or third option of the Administrative Requirement, they would be, contrary to the requirements of law, forced to perform the task of examination themselves, i.e., ensuring that no conflicting claims

⁴ It should be noted that potentially conflicting claims are not deemed unpatentable until one of the applications containing allegedly conflicting claims issues.

exist or resolving all potential conflicts between claims.

The statute and rules clearly impose on the Examiner a duty to examine an application for a patent. There is no legal authority to shift this duty to applicants. The Examiner's argument in the March '01 Communication that the Administrative Requirement requires nothing more than what the applicants "have been and are required to do anyway" is erroneous and misleading. If the Examiner's argument were true, there would be no need to impose the Administrative Requirement — the Examiner could simply reject the claims based on existing rules. The Examiner does not reject the claims based on existing rules because existing rules require the Examiner — not applicants — to examine the application. The unsanctioned Administrative Requirement impermissibly seeks to shift the burden of examination and should be withdrawn for that reason.

**3. Only When The Examiner Has Made A Prima Face Case
May The Burden Shift To The Applicant**

When rejecting claims, the Examiner bears the initial burden of presenting a prima facie case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992). Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant. *Id.* If the Examiner fails to establish a prima facie case, the rejection is improper and will not stand. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

To support obviousness-type double patenting rejections, the Examiner must conduct the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). These factual determinations form the basis for the obviousness-type double patenting analysis. MPEP §804 mandates that the analysis employed in an obviousness-type double patenting determination parallels the factual and legal analysis for a 35 U.S.C. § 103(a) rejection. Thus,

when making obviousness-type double patenting rejections, the Examiner should identify (a) the differences between the inventions defined by the conflicting claims, and (b) the reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue is an obvious variation of the invention defined in the allegedly conflicting claim. MPEP § 804. Therefore, the MPEP procedure for determining whether conflicting claims exist in related applications makes clear that the double patenting analysis is a duty of the Examiner, which may not be forced upon the applicants under threat of abandonment.

4. Administrative Convenience Is Not Sufficient Justification For Imposing The Burden Of Examination On The Applicants

In the instant case, the Examiner's justification for the Administrative Requirement is the apparent burden of addressing and analyzing "millions of claim comparisons." As discussed above, the apparent burden of making claim comparisons is obviated by applicants' extensive submissions to assist and simplify the Examiner's task of comparing claims. Additionally, applicants' abandonment of 169 applications pursuant to the consolidation agreement provides further relief from the workload issue raised by Examiner.⁵ These important points notwithstanding, administrative convenience is simply not a valid reason for avoiding a fact-specific analysis of claims necessitated by a proper obviousness-type double patenting rejection:

Per se rules that eliminate the need for fact-specific analysis of claims and prior art may be administratively convenient for PTO examiners and the Board. Indeed, they have been sanctioned by the Board as well. But reliance on *per se* rules of obviousness is legally incorrect and must cease. Any such administrative convenience is simply inconsistent with section 103, which, according to *Graham* and its progeny, entitles an applicant to issuance of an otherwise proper patent unless the PTO establishes that the invention *as claimed* in the application is obvious over cited prior art, based on the specific comparison of that prior art with claim limitations.

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See footnote 1, *supra*.

In re Ochiai, 71 F.3d 1565, 1572, 37 U.S.P.Q.2d 1127, 1133 (Fed. Cir. 1995); *see also Transco Products Inc. v. Performance Contracting, Inc.*, 38 F.3d 551(1), 32 U.S.P.Q.2d 1077 (Fed. Cir. 1994), *cert. denied*, 513 U.S. 1151 (1995) (“[a]ctions . . . taken by the PTO primarily for administrative convenience, should not increase the burden on an applicant regarding his ability to obtain patent protection”).

Contrary to the Examiner’s assertion, much of the analysis involved in the examination of the first of the related applications is directly applicable to the examination of the other related applications. Due to the overlap in search areas and relevant prior art, the allegation of an undue administrative burden made by the Examiner is simply not justified. No court has ever implied that inconvenience to the PTO could ever be an excuse for foregoing the actual examination of a patent application required for a double patenting rejection.⁶

5. The Chart Of Apparent Conflicts In The Claims Is Insufficient To Support The Administrative Requirement

To the February 3, 1998 Action, the Examiner attaches an appendix which the Examiner contends to be a demonstration of claim conflicts. The appendix fails to demonstrate any conflicts between claims of the **present application** and claims of the co-pending applications. Rather, the office action appendix compares representative claims of **other applications** in an

⁶ The PTO may impose an administrative requirement on patent applicants only under clearly defined and specified circumstances. When an application claims more than one independent and distinct invention, an examiner may impose a restriction requirement pursuant to 35 U.S.C. § 121 to ease the burden of examining that subject matter, thereby requiring an applicant to file one or more divisional applications. Under MPEP § 809.02(a), the examiner may identify each of the disclosed species to which claims are restricted. However, in some cases, such as where a large number of claims exist or the species are not easily discernible, an examiner may identify at least exemplary ones of disclosed species. In such a case, an examiner may impose on an applicant the duty of grouping the claims in appropriate species for administrative convenience. The applicant in such circumstances is assisting the examiner in a formal procedural matter. The recognized PTO procedure of requiring an applicant to divide the claims into groups in response to a restriction requirement is clearly distinguishable from the Administrative Requirement imposed upon applicants. Under the Examiner’s Administrative Requirement in the pending application, the examiner is requiring **substantive determinations of patentability** from the applicants. This task of examination is statutorily reserved for the Examiner, 35 U.S.C. § 131. No authority exists in any part of the Patent Act for its imposition upon an applicant.

attempt to establish that “conflicting claims exist between the 329 related copending applications.” Absent any evidence of conflicting claims between the applicants’ present application and any other of applicants’ co-pending applications, any requirement imposed upon applicants to resolve such alleged conflicts is improper.

B. The Administrative Requirement Is Unsupported By Relevant Legal Authority And Is A Substantive Rule Imposed In Violation Of The Administrative Procedures Act

1. The Terms Of The Administrative Requirement Are Unsupported By 37 C.F.R. § 1.78(b)

The Examiner can not reasonably rely on 37 C.F.R. § 1.78(b) as authority to impose the Administrative Requirement. Rule 78(b) provides that:

Where two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application.

Rule 78(b) requires the elimination of conflicting claims from all but one co-pending application. It cannot be construed to sanction the imposition of the present Administrative Requirement.

In the February 3, 1998 Action, the Examiner did not establish a procedure for the elimination of conflicting claims from all but one application or provide an analysis of such conflicts to effect such elimination. Instead, he has required applicants to: 1) file terminal disclaimers in each of the related applications; 2) provide an affidavit verifying that no conflicts exist; or 3) resolve all conflicts between claims in the related applications. None of the options compelled by the Administrative Requirement is authorized by Rule 78(b). Therefore, applicants respectfully submit that the imposition of such a requirement is improper.

To implement the requirements of Rule 78(b), MPEP § 822.01 directs the Examiner to treat conflicting claims as follows:

Under 37 C.F.R. § 1.78(b), the practice relative to overlapping claims in applications copending before the examiner..., is as follows: Where claims in one application are unpatentable over claims of another application of the same inventive entity because they recite the same invention, *a complete examination should be made of the claims of each application* and all appropriate rejections should be entered in each application, including rejections based upon prior art. *The claims of each application may also be rejected on the grounds of provisional double patenting on the claims of the other application* whether or not any claims avoid the prior art. Where appropriate, the same prior art may be relied upon in each of the applications. MPEP § 822.01 (6th Ed., Rev. 3, 1997), (*emphasis added*).

Contrary to the express directives of MPEP § 822.01 and 37 C.F.R. § 1.78(b), the Examiner here has made no effort to examine the co-pending applications, nor has he made any rejection to achieve the elimination of conflicting claims from all but one co-pending application. He has simply ignored these mandates.

2. The Examiner's Conditioning Of Further Examination And Allowance Of The Applications On Compliance With The Administrative Requirement Exceeds His Authority

The Examiner has stated that failure to comply with the Administrative Requirement will result in abandonment of the present application. Applicants respectfully submit that abandonment of an application can properly occur only:

- (1) for failure to respond within a provided time period (37 C.F.R. § 135);
- (2) as an express abandonment (37 C.F.R. § 138); or
- (3) as the result of failing to timely pay the issue fee (37 C.F.R. § 316).

The PTO rules include no provision permitting abandonment for failure to comply with any of the requirements presented by the Examiner. To impose an improper requirement upon applicants and then to hold the application as abandoned for failure to comply with the improper requirement violates the PTO rules and exceeds the Examiner's authority. Furthermore, the Examiner has created a substantive rule which is above and beyond the rulemaking authority of the PTO, and is therefore invalid.

In the *Application of Mott*, 539 F.2d 1291, 190 U.S.P.Q. 536 (C.C.P.A. 1976), the applicant had conflicting claims in multiple applications. The C.C.P.A. held that action by the Examiner which would result in automatic abandonment of the application was legally untenable. *Id.* at 1296, 190 U.S.P.Q. at 541. In the present application, the Examiner has asserted that there are conflicting claims in multiple applications, and by affirmatively requiring action by the applicants, the Examiner has imposed a condition that will effectively result in an automatic abandonment upon failure to comply with the Administrative Requirement. Therefore, under *Mott's* analysis, the conditional abandonment of this application is legally untenable.

**3. The Examiner's Administrative Requirement Is
An Unlawfully Promulgated Substantive Rule Imposed
In Violation Of The Administrative Procedures Act**

The Administrative Procedure Act, 5 U.S.C. § 555 (1999), (APA), requires federal agencies to publish all substantive in advance for the public's notice and comment. *See generally Paralyzed Veterans of Am. v. West*, 138 F.3d 1434, 1435-1436 (Fed. Cir. 2000) (discussing the notice and comment requirements under §§ 552 and 553 of the APA). Any regulation established by the PTO must comply with the notice and comment requirement imposed by the APA. *See* 35 U.S.C. § 2(b)(B). The Administrative Requirement imposed on applicants is a substantive rule, as that term has been defined by case law interpreting section 553 of the APA, which should be voided for the PTO's failure to comply with the APA.

In contrast to "interpretive rules," which do not require notice and comment, the issuance of "substantive rules" require agencies to publish a proposed rule in the Federal Register and allow for the public's opportunity to comment on the proposed rule. *See* 5 U.S.C. § 553 (1999). The Federal Circuit has described the difference between "substantive rules" and "interpretive rule" as follows:

In general terms, case law has defined “substantive rules” as those that effect a change in existing law or policy or which affect individual rights and obligations. “Interpretive rules,” on the other hand, clarify or explain existing law or regulations and are exempt from notice and comment under section 553(b)(A). As our sister circuit has explained: “[a]n interpretive statement simply indicates an agency’s reading of a statute or rule. It does not intend to create new rights or duties, but only reminds affected parties of existing duties.” *Orengo Caraballo v. Reich*, 11 F.3d 186, 195 (D.C. Cir. 1993) (internal quotes omitted).

Paralyzed Veterans of Am., 138 F.3d at 1436.

The Administrative Requirement at issue goes beyond merely interpreting or clarifying existing PTO regulations because it imposes upon the applicants new duties to make affirmative determinations regarding conflicting claims or file terminal disclaimers at a premature time to avoid abandonment. In fact, far from merely interpreting or clarifying the PTO’s regulations, the terms of the Administrative Requirement directly contradict the PTO’s guidelines addressing the Examiner’s responsibilities regarding double patenting issues. *See* Section III.B.1., *supra*. Contrary to the Examiner’s position articulated in the March ’01 Communication, none of the provisions contained in the Administrative Requirement restate or remind applicants of their existing duties under the PTO’s regulations. Instead, the Administrative Requirement drastically changes the scheme under which the Examiner is required to address double patenting concerns by imposing new obligations on applicants that plainly affect their individual rights and obligations under existing patent laws and regulations.

Additionally, the Examiner and the PTO lack the legislative authority to impose the terms of the Administrative Requirement even if the PTO complied with the provisions of the APA. Because the PTO lacks the requisite statutory authority to issue substantive rules, the PTO cannot unilaterally impose the Administrative Requirement, which substantively changes the applicants’ rights and obligations under the patent laws.

A fundamental premise of administrative law is that administrative agencies must act solely within their statutory grant of power. *See Chevron v. Natural Resources Defense Council*, 467 U.S. 837, 842-845 (1984). The PTO's authority to establish regulations are set forth in 35 U.S.C. § 2(b)(2) (West 2001). Under section 2(b)(2), the PTO can only issue regulations that "govern the conduct of the proceedings in the [PTO]" and govern other procedural aspects of the application process. *Cf. Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 930, 18 U.S.P.Q.2d 1677, 1686 (Fed. Cir. 1991) (concluding that the broadest grant of rulemaking authority (at the time, 35 U.S.C. § 6(a) permitting the Commissioner to promulgate regulations directed to "the conduct of proceedings" in the PTO) does not grant the Commissioner authority to issue substantive rules of patent law).

As the PTO Commissioner has no power to promulgate substantive rules, the Commissioner receives no deference in his interpretation of the statutes and laws that allegedly give rise to the instant requirement. *See Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996), citing, *Chevron v. Natural Resources Defense Council*, 467 U.S. 837 (1984). When agency rules either (a) depart from existing practice or (b) impact the substantive rights and interests of the affected party, the rule must be considered substantive. *See National Ass'n of Home Health Agencies v. Scheiker*, 690 F.2d 932, 949 (D.C. Cir. 1982), *cert. denied*, 459 U.S. 1205 (1983). The Administrative Requirement is clearly a substantive rule impacting applicants' rights and interests under the patent laws.

a. The Administrative Requirement Is Substantive Because It Radically Changes Long Existing Patent Practice By Creating A New Obligation Upon Applicants Not Authorized By 37 C.F.R. § 1.78(b)

The Examiner's Administrative Requirement departs from long existing practice under 37 C.F.R. § 1.78(b), because (1) it creates and imposes a new obligation on applicants to avoid

abandonment of the application based on the unsupported allegation that conflicts exist between claims of the related co-pending applications, and (2) it effectively creates a final double patenting rejection result without requiring the PTO to affirmatively make a double patenting rejection. Long existing patent practice recognizes only two types of double patenting: 1) double patenting based on 35 U.S.C. § 101 (statutory double patenting) and 2) double patenting analogous to 35 U.S.C. § 103 (the well-known obviousness type double patenting).⁷ These two well established types of double patenting use an objective standard to determine when they are appropriate⁸ and have a determinable result on the allowability of the pending claims.

The Examiner's new Administrative Requirement represents a radical departure from long existing patent practice relevant to conflicting claims between co-pending applications of the same inventive entity. The two well established double patenting standards are based on the conduct of an objective analysis of comparing pending and allowed claims. However, in the present application, there are no **allowed** claims and the Examiner has not conducted any objective analysis of the claims. The Examiner's requirement to avoid a double patenting rejection presumes that conflicts exist between pending claims in the present application and pending claims in the co-pending applications. This presumption of conflicts between claims represents a radical departure from long existing patent practice as defined by 37 C.F.R.

§ 1.78(b), which states:

⁷ M.P.E.P. § 804(B)(1) states, in an admittedly awkward fashion, that the inquiry for obviousness type double patenting is analogous to a rejection under 35 U.S.C. § 103: "since the analysis employed in an obvious-type double patenting determination parallels the guidelines for a 35 U.S.C. § 103 rejection, the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obvious-type double patenting analysis".

⁸ The objective test for same invention double patenting is whether one of the claims being compared could be literally infringed without literally infringing the other. The objective test for obviousness type double patenting is the same as the objective nonobviousness requirement of patentability with the difference that the disclosure of the first patent may not be used as prior art.

Where two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application.

Clearly, the only requirement authorized by the rule is the elimination of conflicting claims from all but one application where conflicting claims have been determined to exist. Furthermore, in order to determine that conflicting claims do in fact exist in multiple applications, the only possible analysis is obviousness-type double patenting, since there are no allowed or issued claims by which to employ the 35 U.S.C. § 101 statutory double patenting analysis. Once obviousness-type double patenting analysis has been applied and conflicting claims have been determined to exist, M.P.E.P. § 804 mandates that only a **provisional** obviousness-type double patenting rejection is possible until claims from one application are allowed.

In summary, the Examiner's new Administrative Requirement departs from long-established practice. As such, the Examiner's Administrative Requirement is a substantive rule beyond the authority of the PTO and imposed in violation of the APA.

b. The Administrative Requirement Is A Substantive Rule Because It Adversely Impacts The Rights And Interests of Applicants Under The Patent Laws

The rights and benefits accorded to an owner of a U.S. patent are solely statutory rights. *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543 (Fed. Cir. 1996). The essential statutory right in a patent is the right to exclude others from making, using and selling the claimed invention during the term of the patent. Courts have recognized that some purported new procedural rules of the PTO are actually substantive rules, e.g., when the new rule made a substantive difference in the ability of the applicant to claim his discovery. See *Fressola v. Manbeck*, 36 U.S.P.Q.2d 1211, 1214 (D.D.C. 1995) (citing *In re Pilkington*, 411 F.2d 1345, 1349; 162 U.S.P.Q. 145 (C.C.P.A. 1969) and *In re Steppan*, 394 F.2d 1013, 1019; 156 U.S.P.Q. 143 (C.C.P.A. 1967)).

The Administrative Requirement, on its face and as applied here, is an instance of a PTO rule resulting in a substantive difference in applicants' ability to claim their invention and, therefore, must be considered a substantive rule. The Administrative Requirement imposes unwarranted obligations or requirements on the applicants and denies applicants' rights and benefits expressly conferred by the patent statute. The measure of the value of these denied rights and benefits is that the Administrative Requirement, as applied here, would deny applicants the full and complete PTO examination of applicants' claims on their merits, as specified by 37 C.F.R. § 1.105. To require applicants to file terminal disclaimers in each related application terminally disclaiming each of the other applications based on the PTO's incomplete examination on the merits would deny applicants the benefit of the full patent term of 17 years on each of the applicants' respective applications. To require applicants to resolve all conflicts compels them to narrow their claims without the benefit of a substantive determination regarding

how the Examiner may potentially interpret applicants' claims. Indeed, to require applicants to resolve all potential conflicts, where no conflicts have been identified, denies applicants the benefit of the full scope of the pending claims. Applicants respectfully submit that the Administrative Requirement has a profound impact on their rights and interests in the presently claimed invention.

C. Conclusion Regarding The Administrative Requirement

By imposing the Administrative Requirement on applicants, the Examiner has reversed the statutorily imposed scheme governing examination by improperly shifting the burden of examination to the applicants. The imposition of this obligation on the applicants, which has a serious impact on their interests and substantive rights under the patent laws and regulations, is not justified by the circumstances or supported by 37 C.F.R. §§ 1.56, 1.63, 1.78(b) or other applicable legal authority. Without justification or authority, the Examiner has imposed a requirement affecting applicants' substantive rights and obligations that exceeds the PTO's statutory authority and violates the requirements of the APA.

V. ANY FURTHER RESPONSE TO THE ADMINISTRATIVE REQUIREMENT SHOULD BE DEFERRED IN ORDER TO ADVANCE PROSECUTION

Even if the PTO's stance on the Administrative Requirement was proper and within its statutory authority — which applicants adamantly maintain is not the case — any compliance with the Administrative Requirement should be deferred because compliance at this stage hinders the advancement of prosecution. This is because the claims may not be in their final form, and the filing of terminal disclaimers based on claims that may change is premature and counterproductive.

The MPEP directives regarding double patenting rejections spell out a straightforward procedure that is clearly intended to streamline prosecution. First, to implement the

requirements of Rule 78(b), which addresses conflicting claims among applications, MPEP

§ 822.01 directs the Examiner to treat conflicting claims as follows:

Where claims in one application are unpatentable over claims of another application of the same inventive entity because they recite the same invention, *a complete examination should be made of the claims of each application* and all appropriate rejections should be entered in each application, including rejections based upon prior art. *The claims of each application may also be rejected on the grounds of provisional double patenting on the claims of the other application* whether or not any claims avoid the prior art. MPEP § 822.01 (7th Ed., July, 1998), (*emphasis added*).

As set forth above in Section IV, the Examiner here has made no effort to examine the co-pending applications nor made any rejection to achieve the elimination of conflicting claims from all but one co-pending application. He has simply ignored these mandates.

That notwithstanding, once the Examiner has identified conflicting claims, MPEP § 822.01 then mandates that only a **provisional** obviousness-type double patenting rejection is to be made, and that the provisional rejection is to be maintained until claims from one application are allowed:

The “provisional” double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that “provisional” double patenting rejection is the only rejection remaining in one of the applications. If the “provisional” double patenting rejection in one application is *the only rejection remaining* in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the “provisional” double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent. MPEP § 822.01 (7th Ed., July, 1998), (*emphasis added*).

Therefore, the MPEP requires that only a **provisional** double patenting rejection is to be issued until all other bases for rejection (e.g., 35 U.S. C. §§ 102, 103, 112) are removed. The clear import of this requirement is that imposing a nonprovisional double patent rejection before that point would be **counterproductive to orderly advancement of prosecution**.

Premature imposition of a nonprovisional double patenting rejection is counterproductive

because pending claims may undergo significant amendment (or even cancellation) based on, e.g., statutory rejections under §§ 102, 103 and 112, and so forth.

For example, amendments and cancellations of the claims in response to statutory rejections will often remove preexisting conflicts, thereby rendering a previously-made provisional double patenting rejection moot. In that scenario, not only have the applicants and PTO wasted valuable resources in addressing a later-mooted double patenting issue, but applicants may have unnecessarily terminally-disclaimed a portion of his/her patent term.

In the application at hand, the claims have not been allowed and, therefore, the claims are quite possibly not in their final form. Therefore, resolution of any potential double patenting issues is premature and should be deferred until the claims are otherwise in condition for allowance.

In summary, the MPEP clearly requires that the Examiner can issue double patenting rejections only as provisional rejections until all other rejections have been resolved. Applicants respectfully request that any further action demanded by the PTO in response to the Administrative Requirement be deferred until the claims are deemed to be otherwise allowable.

VI. FOR THE EXAMINER TO ACT TO ABANDON THIS APPLICATION WOULD BE PREMATURE WHEN THE ISSUE OF THE ADMINISTRATIVE REQUIREMENT IS PRESENTLY PENDING BEFORE THE COMMISSIONER ON PETITION

On March 7, 2000, applicants filed a petition to the Commissioner under 37 C.F.R. § 1.181 for application serial number 08/470,571 requesting that the Examiner be required to withdraw the Administrative Requirement as improper. Thus, this petition has been pending with the Commissioner for nearly 18 months and likely will result in a decision in the near future.

In view of the fact that this issue is now before the Commissioner on a related

application, any decision by the Examiner to abandon this application based on the Administrative Requirement would be premature. It is in both the PTO's and applicants' best interests to defer any such decision on the present application until the Commissioner makes a final determination on the above petition.

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Any. Docket No. 05634.0145

VII. CONCLUSION

Applicants respectfully request withdrawal of the determination in the March '01 Communication that applicants' prior filings were nonresponsive and earnestly solicit reconsideration and allowance of the instant application.

Respectfully submitted,

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Date: August 21, 2001